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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
LONG, SCOTT	

ART UNIT	PAPER NUMBER
1633	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/582,279	KLOCK ET AL.	
	Examiner	Art Unit	
	Scott D. Long	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 8-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 8-16* is/are rejected.

7)☒ Claim(s) *1 and 8-12* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *6/9/2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Examiner acknowledges the election, with traverse, of Group I (claims 1 and 8-16), drawn to isolated nucleic acids comprising SEQ ID NO:1; pharmaceutical preparation thereof; diagnostic kit; and method of manufacture., in the reply filed on 23 July 2007.

The applicant traverses the lack of unity, based on the following: (A) the groups identified by the examiner are all recited in claim 1; (B) the examiner has not adequately explained both that there are different groups of claims present in the application and why each of the groups lacks unity relative to each other group; (C) restriction may compel the PTO to issue numerous patents, some of which may present potential double patenting issues; and (D) there is no serious search burden to examine all groups.

In response to argument A, the examiner reminds the applicant that there is nothing in the MPEP or Patent Cooperation Treaty that prevents restriction within a claim, when multiple inventions are presented in a single claim. In response to argument B, the examiner points out that the previous Restriction (Lack of Unity) Action (filed 6/21/2007) indicated that the examiner indicated reasons why the invention lacked unity. Particularly, as cited on pages 3-5 of the Restriction Action (filed 6/21/2007), the examiner wrote, "The inventions are drawn to multiple methods and multiple products, therefore as per 37 CFR § 1.475(a)-(d), applications containing claims drawn to more

than one categories of invention (as defined by section (b)) are not considered to have unity of invention (see particularly section (c)). See the following:

37 CFR § 1.475 Unity of invention before the International Searching Authority, the International Preliminary Examining Authority and during the national stage.

(a) An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

(b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or
(2) A product and process of use of said product; or
(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
(4) A process and an apparatus or means specifically designed for carrying out the said process; or
(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

(c) If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.

(d) If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and § 1.476(c).

The instant claims contain multiple products (for example, nine distinct isolated nucleic acids SEQ ID NO:1-9) and methods of manufacturing nine distinct isolated nucleic acids.

As described in the previous Restriction Action, the nucleic acid sequences are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleic acid is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. The applicant has provided no evidence to show that the claimed nucleic acids are obvious variants. Therefore, the examiner believes the multiple produces and multiple methods of manufacture are claimed, there is no unity of invention or inventive step.

In regard to argument C, it is not a burden to the Office to issue multiple patents to inventors when restriction has been required. In addition, the Office cannot assert obvious double patenting, when restriction was required in an application.

The examiner has carefully examined the claimed sequences SEQ ID NO:1-9 and is partially persuaded by the applicants' arguments. The examiner has concluded that SEQ ID NO:1 and SEQ ID NO:2 are merely the DNA and RNA forms of aptamer 89. Because the differences between these two nucleic acid sequences are not truly burdensome to search, the ***examiner has rejoined groups I and II***. While there is strong similarity between SEQ ID NO:4 and SEQ ID NO:2, the 3' end is sufficiently different that the examiner is not sure whether a sequence search of SEQ ID NO:1 would properly search for SEQ ID NO:4. Therefore, no other sequences will be rejoined with Groups I-II. Each of the remaining nucleic acid sequences, SEQ ID NO:3-9

requires a separate search through numerous databases. This is burdensome for the examiner.

Therefore, the examiner finds the remainder of the applicants' traversal unpersuasive and the modified restriction is made final.

Claim Status

Claims 1 and 8-16 are pending. Claims 1 and 8-16 are under current examination.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

> The oath or declaration is defective because: The oath is not in English and does not seem to identify the instant application on the oath. A replacement oath is required.

Information Disclosure Statement

The Information Disclosure Statements (IDS) filed on 27 September 2006 consisting of 2 sheets are in compliance with 37 CFR 1.97. Accordingly, examiner has considered the Information Disclosure Statements.

Priority

This application claims benefit from as a 371 of PCT/EP04/14097 (filed 12/10/2004). In addition, the application claims benefit from foreign application GERMANY DE 103 58 407.2 (filed 12/11/2003). The instant application has been granted the benefit date, 10 December 2004, from the application PCT/EP04/14097.

Sequence Compliance

Sequence Listing and CRF have been received and are acknowledged by examiner. A statement that the Computer Readable Form (CRF) and the Sequence Listing are identical has been submitted and is acknowledged by examiner.

However, the Claims and Specification do not conform to sequence rules, requiring the use of "SEQ ID NO:" (37 CFR 1.821-1.825).

Where the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO:" in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application. 37 CFR 1.821 (d)

The applicant is reminded that claims and specification must be amended in order to comply with regulations cited above. All references to sequences in claims and specification should be referred to as "SEQ ID NO:1", for example. To avoid all doubts

of the examiner and to ensure correct interpretation of the claims and specification, the identification of sequences with proper sequence identifiers is required.

Specification

The disclosure is objected to because the Specification does not conform to sequence rules, requiring the use of "SEQ ID NO:" (37 CFR 1.821-1.825). Appropriate correction is required.

The abstract of the disclosure is objected to because the first line of the abstract has an additional period in it. Correction is required. See MPEP § 608.01(b).

The specification does not contain a section, "brief description of drawings." This must be added, since there are drawing submitted with the application. In addition, because the polynucleotides illustrated in the Drawings are not identified in the Drawings, it is vital that the detailed description of the drawings contains identification of these polynucleotide sequences by their appropriate SEQ ID NO.

Claim Objections

Claims 1 and 8-12 are objected to because of the following informalities:

Claim 1 begins with "nucleic acid," but ends with "this nucleic acids." There is a grammatical agreement issue with this language; the final recitation should refer to the singular nucleic acid, "this nucleic acid," for example.

Claims 8-12 recite the phrase, "less nucleotides" in line 1 of the respective claims. This is a grammatical error; "less" is an adverb, placed in a context that more properly requires an adjective, such as "fewer." Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 13 recites the phrase, "selected from those of." This phrase is indefinite. The term, "those" could lack antecedent basis, since it is not clear what is being referred to. Claim 13 is not written in a proper Markush-type language, such as "An isolated nucleic acid comprising a polynucleotide sequence selected from a group consisting of SEQ ID NO:1-9." Therefore, it is not clear what are the metes and bounds of "those." The SEQ ID NOs are not isolated nucleic acids, so the claim language, as currently written, does not properly join the beginning and end of the claim in a way that makes clear what is being claimed. Appropriate correction is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 8-12 and 14-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The methodology for determining adequacy of Written Description to convey that applicant was in possession of the claimed invention includes determining whether the application describes an actual reduction to practice, determining whether the invention is complete as evidenced by drawings or determining whether the invention has been set forth in terms of distinguishing identifying characteristics as evidenced by other descriptions of the invention that are sufficiently detailed to show that applicant was in possession of the claimed invention (*Guidelines for Examination of Patent Applications under 35 USC § 112, p 1 "Written Description" Requirement;* (Federal Register/Vol 66. No. 4, Friday, January 5, 2001; II Methodology for Determining Adequacy of Written Description (3.)).

Claim 1 is broadly drawn, such that it applies to any a genus of functional variations of SEQ ID NO:1-2. However, there are seems to be only one working example (Example 7, SEQ ID NO:4) of a functional variation of SEQ ID NO:1-2 provided in the instant application.

The specification states, "A further embodiment of the present invention concerns functional variations of these nucleic acids. These are, for the purposes of the present

invention, nucleic acids which show a range of a least 6, preferably at least 10, very preferably at least 15 and most preferably of all at least 20 consecutive nucleotides, which exhibit at least 60%, preferably at least 70%, very preferably at least 80%, even more preferably at least 90% and most preferably of all at least 95% sequence identity to the sequences selected from the group consisting of: SEQ ID NO 1 to SEQ ID NO 9, and which, in the test procedure described below, exhibit an anti-apoptotic activity of at least 50% inhibition index, preferably at least 60%, very preferably at least 70%, even more preferably at least 80%, more preferably still at least 90% and most preferably of all at least 95%." (page 5, lines 1-11). The specification further indicates that functional variations comprise isolated nucleic acids selected from the group consisting of SEQ ID NO:1-9 and further comprising extensions of said isolated nucleic acids "not more than 100, preferably not more than 70, especially preferably not more than 30, very especially preferably not more than 20 and most preferably of all not more than 10 nucleotides." (page 5, lines 15-17).

While SEQ ID NO:4 seems to fit the definition of a functional variant, having a high percentage sequence identity and having anti-apoptotic activity (Example 7, pages 17-18), this seems to be the only sequences provided in the specification which is a functional variant of SEQ ID NO:1 or SEQ ID NO:2.

Because aptamer activity is based on high affinity binding to specific targets, and the specification has not identified the important motifs required for anti-apoptotic activity.

The Revised Interim Guideline for Examination of Patent Applications under 35 USC § 112, p1 "Written Description" Requirement (Federal Register/ Vol 66. No 4, Friday January 5, 2001) states "THE CLAIMED INVENTION AS A WHOLE MAY NOT BE ADEQUATELY DESCRIBED IF THE CLAIMS REQUIRE AN ESSENTIAL OR CRITICAL ELEMENT WHICH IS NOT ADEQUATELY DESCRIBED IN THE SPECIFICATION AND WHICH IS NOT CONVENTIONAL IN THE ART" (column 3, page 71434), "WHEN THERE IS SUBSTANTIAL VARIATION WITHIN THE GENUS, ONE MUST DESCRIBE A SUFFICIENT VARIETY OF SPECIES TO REFLECT THE VARIATION WITHIN THE GENUS", "IN AN UNPREDICTABLE ART, ADEQUATE WRITTEN DESCRIPTION OF A GENUS WHICH EMBRACES WIDELY VARIANT SPECIES CANNOT BE ACHIEVED BY DISCLOSING ONLY ONE SPECIES WITHIN THE GENUS" (column 2, page 71436, emphasis added).

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "APPLICANT MUST CONVEY WITH REASONABLE CLARITY TO THOSE SKILLED IN THE ART THAT, AS OF THE FILING DATE SOUGHT, HE OR SHE WAS IN POSSESSION OF THE INVENTION. THE INVENTION IS, FOR PURPOSES OF THE 'WRITTEN DESCRIPTION' INQUIRY, *WHATEVER IS NOW CLAIMED*." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize the [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Considering the potentially large numbers of polynucleotides encompassed by these claims, the disclosure is not sufficient to show that a skilled artisan would

recognize that the applicant was in possession of the claimed invention (genus) commensurate to its scope at the time the application was filed.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1 and 8-15 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claimed "nucleic acid" lacks the "hand of man." See MPEP 2105. A more preferred manner of claim language might be, for example, "An isolated polynucleotide having anti-apoptotic activity and comprising a nucleic acid sequence selected from the group consisting of SEQ ID NO:1-9, and functional variations thereof." As currently written, not being isolated, the claims are non-statutory. Although the method of claim 16, clearly claims a statutory method of manufacturing an isolated nucleic acid, it would be preferable to keep claim language consistent, by also introducing the word "isolated" before "nucleic acid of claim 1."

Conclusion

No claims are allowed.

Examiner Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Scott Long** whose telephone number is **571-272-9048**. The examiner can normally be reached on Monday - Friday, 9am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Woitach** can be reached on **571-272-0739**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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